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Letter dated 3 February 2014 from the Chargé d'affaires a.i. of the Permanent Mission of Germany to the United Nations addressed to the President of the Security Council

Within the framework of the "Wiesbaden Process", the Government of Germany hosted a second industry outreach conference on Security Council resolution 1540 (2004) in Wiesbaden, Germany, on 3 and 4 December 2013, focusing on biosecurity. The international conference was organized in cooperation with the United Nations Office for Disarmament Affairs and the European Commission's European Union-Outreach in Export Control of Dual-Use Items programme, the latter being represented by the Federal Office of Economics and Export Control.

In its resolution 1977 (2011), the Security Council explicitly encouraged the 1540 Committee to draw also on relevant expertise, including civil society and the private sector (para. 12). In this context, industry is an important stakeholder and partner in combating the proliferation of weapons of mass destruction to non-State actors.

The conference provided a lively and substantive exchange on biosecurity issues related to the implementation of non-proliferation policies. The 70 participants benefited from an enhanced understanding of the motives and objectives of other actors in the field. While industry representatives gained insight into the motivation behind and the provisions of Security Council resolution 1540 (2004), its implementation and the work of the 1540 Security Council Committee, participants from Government, international organizations and academia gained a better understanding of the challenges in this sector as well as industry practices and initiatives.

The outcome of these valuable debates is summarized in the report which is attached to the present letter and which was drafted under our responsibility (see annex). We would be grateful if you could circulate the present letter and its annex among the members of the Security Council and issue them as a document of the Council.

(*Signed*) Heiko **Thoms**

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Annex to the letter dated 3 February 2014 from the Chargé d'affaires a.i. of the Permanent Mission of Germany to the United Nations addressed to the President of the Security Council

Risks, challenges and responses: Industry's effective practices in responding to biosecurity risks

A Conference in Support of Implementing Security Council resolution 1540 (2004)

Wiesbaden, Germany

3 and 4 December 2013

Industry can be an important stakeholder and partner in combating the proliferation of weapons of mass destruction to non-State actors, as it is in many cases the direct addressee in implementing Security Council resolution 1540 (2004). Therefore, in its resolution 1977 (2011), the Security Council explicitly encouraged the 1540 Committee to draw also on relevant expertise, including civil society and the private sector (para. 12).

The Government of Germany hosted the first international industry outreach conference on resolution 1540 (2004) in April 2012 in the city of Wiesbaden. While the 2012 Wiesbaden Conference was aimed at strengthening the partnership between government and industry in general, the 2013 conference focused on aspects of 1540 implementation in the area of biosecurity. The conference was again organized in cooperation with the United Nations Office for Disarmament Affairs and the European Commission's European Union-Outreach in Export Control of Dual-Use Items programme, the latter being represented by the Federal Office of Economics and Export Control.

The approximately 70 participants included representatives of international and national industry associations, global enterprises, regional biosafety organizations, Governments and civil society. The 1540 Committee was represented by two Committee Experts and a statement was delivered on behalf of the 1540 Committee Chair, Ambassador Oh Joon.

The timeliness of this two-day conference was reflected in lively discussions throughout the event, spanning a range of issues related to combating biological weapons such as non-proliferation, counter-proliferation and consequence management as well as other multi-stakeholder initiatives related to biological risk management. Various presentations covered a wide area of topics such as an overview of Security Council resolution 1540 (2004) obligations and the role of the industry in countering biological risks and threats (i.e., risk and threat awareness; prevention and protection; surveillance and detection; response and recovery); the impact of (and industry's contribution to) the implementation of national controls on biological weapons-related materials; the convergence of biology and chemistry and its implications; chemical and biological non-proliferation regimes; responsible conduct of dual-use research of concern; the use of open-source synthetic biology and export control regulations in the do-it-yourself biology community; personnel reliability measures; corporate, institutional or industry-wide codes of conduct; corporate social responsibility/responsible care as well as self-regulation.

The conference provided a substantive exchange on biosecurity issues related to the implementation of non-proliferation policies. While industry representatives gained insight into the motivation behind and the provisions of resolution 1540 (2004), its implementation and the work of the 1540 Committee, representatives from Government, international organizations and academia gained a better understanding of the challenges in this sector as well as industry's practices and initiatives.

This in turn resulted in active debate among industry, regional biosafety associations, international organizations and civil society representatives on security-related aspects of the life sciences and biotechnology. Several areas were identified as requiring further work and synergy of efforts to boost the implementation of resolution 1540 (2004) in the area of biosecurity:

(a) The complexity created by differences in regulatory safety and security approaches and a high number of overlapping regulations can present a major burden for biological research and development as well as vaccine manufacturing, not only in developed countries but also in developing countries where this complexity may be perceived as delaying economic development and interfering with the conduct of legitimate trade;

(b) Limited safety awareness, especially in biological research and development communities; therefore, there is a need to improve safety awareness among institutions and persons in order to lay the ground for the development and implementation of State regulations in a bottom-up effect;

(c) The creation of codes of conduct to establish security awareness as an effective industrial practice, in particular in areas that are beyond governmental regulation;

(d) Increased risk of bypassing existing international transportation safety and security regulations by changing, intentionally or unintentionally, the classification of biological materials of concern;

(e) Discrepancies in regulatory genetic engineering frameworks for do-it-yourself biology communities between Europe and other regions of the world;

(f) The need for continuous safety and security risk assessment and oversight of dual-use research of concern experiments;

(g) The lack of clarity and differing interpretation of controls of (intangible) know-how transfer in publishing research results, especially inconsistent application of export control exceptions when publishing fundamental (basic or applied) research;

(h) The improvement of the synergy and coordination among Security Council resolution 1540 (2004), the Biological Weapons Convention, the World Health Organization (WHO) International Health Regulations and the World Organization for Animal Health (OIE) Performance of Veterinary Services, in their national implementation and concerted action on capacity-building/assistance to States; this could also include a harmonization of definitions and concepts used by different stakeholders in this field;

(i) The facilitation of cooperation between industry and civil society with law enforcement at both the national and the international levels (for example,

between the Australia Group and the International Criminal Police Organization (INTERPOL));

(j) While compliance with national and international regulations is dealt with more effectively by large corporations, small enterprises may benefit from closer interaction with professional (biosafety) and industrial associations; biosafety organizations could use more advocacy for their work by States or international organizations;

(k) Biorisk management in Africa may be strengthened by improving social mobilization and awareness-raising/education;

(l) International organizations (including the 1540 Committee) should create better opportunities for regional cooperation and sharing effective practices in public-private partnerships, including civil society;

(m) The 1540 Committee could improve the international biorisk management framework by compiling examples of legislation, regulations and voluntary initiatives (i.e., codes of conduct and biosafety/biosecurity guidance from international organizations) and listing them on its website;

(n) There is a need to move beyond advocacy and awareness-raising towards effective (sustainable, cost-effective, integrated with other non-proliferation and health policies) implementation of the biosecurity areas of resolution 1540 (2004), in particular by developing a government-wide biosafety/biosecurity national framework with input from civil society.

Discussions reflected the sometimes conflicting interests among government, which seeks to maintain high levels of security; industry, which requires consistent rules to operate; and science, which demands as much freedom as possible.

In developed countries, biosecurity and biosafety are usually densely regulated fields, supplemented by self-imposed codes of conduct, which industry perceives as increasing competitiveness in the market. In developing countries and emerging economies, other conditions prevail with regard to political prioritization, security awareness, resources and competitiveness in the field of biosecurity. This is why the implementation of 1540 measures may have lower priority than more pressing issues relating to economic development. In this context, discussions highlighted the potential role of civil society in support of the implementation of resolution 1540 (2004) at the international, regional and national levels. At the same time, it was repeatedly stressed that any control or regulatory measures concerning biological weapons-related materials must be designed to be risk-based and proportionate so as not to impede legitimate trade and the peaceful and beneficial conduct of life sciences research and development activities.

In fact, industry is very much looking for clear and simple rules, guidance, as well as a level playing field. The diverse and very engaged audience at this conference also highlighted the potential role of a comprehensive societal approach in countering biological threats, and their collective and individual efforts towards mitigating the risk (inside and outside the laboratory) posed by science and technology, biological materials, and research-related information, either due to misuse for hostile purposes or the accidental exposure of individuals and the environment to hazardous biological agents.

The comprehensive implementation of resolution 1540 (2004) and the involvement of all relevant stakeholders — explicitly including industry — remains an important concern of the Government of Germany, which is why this "Wiesbaden Process" was initiated in cooperation with the United Nations Office for Disarmament Affairs. The potential for cooperation with industry is to be enhanced further. Therefore, the Government of Germany is prepared to continue this process and host or co-host further conferences. These could take place abroad and in cooperation with other States and could have a thematic or regional focus.